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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,226	05/08/2001	Jeffry G. Weers	0073.00	4017

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EXAMINER
WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,226	WEERS ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/2/03* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-32 and 44-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-32 and 44-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-5, 8-32 and 44-71 are pending. The Amendment filed 12/20/02, Paper No. 11, cancelled claims 6-7, 33-42, amended claims 1, 10-12, 14, 16-17, 31-32, 44, 52, and added claims 53-71.

The Declaration filed 12/2/02, Paper No. 12, is persuasive to overcome the 35 USC 103 rejections in the previous Office Action.

The Applicant's Amendment and Arguments filed 12/2/02, Paper No. 12, are sufficient to overcome the 35 USC 112 rejections in the previous Office Action. Regarding, missing claim 43, Applicant states, "Regarding claim 43, Applicants respectfully request the Examiner renumber the claims as the claims have been misnumbered". Upon allowance of the claims, the Examiner will renumber the claims.

Applicant's arguments with respect to the 35 USC 103 and double patenting rejections over claims 1-5, 8-32 and 44-71 in the previous Office Action, have been considered but are moot in view of the new ground(s) of rejection.

The Objection to the Declaration is withdrawn, as Applicants have provided the post office address of each inventor.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 8-22, 27-32, and 44-52, 59-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-23, 25, 27, 28-30, 34-37, 41-45 of copending Application No. 09/568818. Although the conflicting claims are not identical, they are not patentably distinct from each other. '818 teaches a microparticle comprised of a metal ion-lipid complex and particulate compositions thereof. '818 teaches calcium as its metal ion and phoshatidylcholine (a saturated phospholipid) as its lipid complex. '818 fails to teach an amount effective to increase the gel-to-liquid crystal transition temperature of the particle compared to particles without the divalent cation, wherein the particulate composition is storage stable. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach such a limitation in the invention of '818 because '818 and the instant claims teach the same composition comprising the same constituents. Thus, the composition of '818 must have these properties, as a compounds and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-9, 15, 19-25, 27, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Eistetter (AU 714998).

Eistetter teaches a process for the production of powdered pulmonary surfactant preparations. Exemplified is a powder comprising 7g dipalmitoyl phosphatidylcholine, 205mg of calcium chloride dihydrate and 250 mg palmitic acid. The particle size range is disclosed as between 1-5 micrometers. Thus Eistetter and the instant invention both teach compositions comprising saturated phospholipid (dipalmitoyl phosphatidyl choline), polyvalent cation (calcium chloride dihydrate), and fatty acid (palmitic acid) in particulate form (powder). See pages 7-9.

Regarding the phrase "in an amount effective to increase the gel-to-liquid crystal transition temperature of the particle compared to particles without the polyvalent cation, wherein the particulate composition is storage stable", the Examiner respectfully points out that this property is inherent. Since a compound and its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), and since Eistetter teaches the combination of a saturated phospholipid and polyvalent cation in particulate form, his composition must inherently display the above properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 8-9, 10-32, 44-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers et al. (6,309,623).

Weers et al. teach a stable respiratory dispersion for pulmonary delivery of one ore more bioactive agents comprising a suspension medium having dispersed therein a plurality of perforated microstructures having a mean aerodynamic diameter of less than 5 micrometers and comprising at least one bioactive agent. The perforated microstructures are disclosed as comprising 10% surfactants, wherein surfactants are selected from phospholipids, nonionic detergents, nonionic block copolymers, ionic surfactants, and combinations thereof. Dipalmitoylphosphatidylcholine is disclosed as a phospholipid surfactant, and poloxamer is disclosed as a surfactant. Dipalmitorylphosphatidyl choline is disclosed as a saturated lipid (see Col. 10, line 50). Inorganic salts such as calcium chloride are disclosed as optional excipients, which adjust the pH. Budesonide, fluticasone propionate, salmeterol, and formoterol are disclosed as bioactive agents that can comprise from 5-90% of the composition. Polyvinyl alcohols, polyvinyl pyrrolidones, and polysaccharides are disclosed as additional constituents of the perforated microstructures. The suspension medium is disclosed as primarily comprising fluorinated propellants. The density differential of the particles is disclosed as being less than 0.05g/cm3. The dispersions are disclosed for use in administration to the lung of a patient in need of such treatment, using a metered dose inhaler. The reference lacks an exemplification of a composition comprising a saturated phospholipid and a polyvalent cation. See Col. 4, line 5-Col. 8, line 65; Col. 11, lines 25-42; Col. 16, line 28-Col. 20, line 20; Col. 24, line 56-Col. 25, line 5; Col. 40, line 54-Col. 41, line 55.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify a suspension medium comprising calcium chloride and dipalmitoylphosphatidyl choline because Weerse et al. exemplify a composition comprising dipalmitoylphosphatidyl choline and they teach that adding salts fine tunes the stabilized dispersions for maximum life and ease of administration.

Claims 1-3, 8-9, 15-17, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gould-Fogerite et al. (5,994,318).

Gould-Fogerite et al. teach a composition comprising a biologically relevant molecule and a negatively charged lipid component and a divalent cation component. The biologically relevant molecule can be a saturated fatty acid or amphotericin. Phosphatidylserine and phosphatidylglycerol are disclosed as preferred lipid components. The lipid components are saturated, see Figures 1 and 2, and Col. 16, line 58-60. Calcium, magnesium, and zinc are disclosed as preferred divalent cations. Unit dose powders and granules are disclosed as pharmaceutical forms of the composition. See abstract; Col. 1, line 66-Col. 8, line 30; Col. 9, line 34-Col. 10, line 26. The reference lacks particles of the saturated phospholipid and polyvalent cation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the composition in the form of particles because Gould-Fogerite et al. teach that the composition can be in the form of particles (unit dose powders and granules); thus, one of skill in the art would be motivated to exemplify the composition in the form of particles because of the expectation of achieving a unit dose powder that can deliver biologically relevant molecules to the pulmonary system.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
January 27, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

2/7/03